Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Investigating the effect of probiotic supplementation on clinical manifestations and laboratory findings and the treatment process of patients with Brucellosis: A triple-blind randomized controlled trial

Protocol summary

Study aim

Investigating the effect of probiotic supplementation on clinical manifestations and laboratory findings and the treatment process of patients with Brucellosis

Design

Clinical trial with control group, with parallel and equal groups, Triple blind, randomized by the website "random.org", on 100 patients.

Settings and conduct

Patients referring to the educational-therapeutic centers of Arak city, who are diagnosed with acute brucellosis based on clinical manifestations, epidemiological factors and serological tests, and who meet other inclusion criteria, are included in the trial after obtaining informed consent. These patients are placed in one of the intervention or control groups based on randomization, and according to the group in which the patient is placed, 60 probiotic or placebo capsules placed in similar cans are delivered to them, which will be used 1 capsule daily for 60 days.

Participants/Inclusion and exclusion criteria

New patients with brucellosis between 18 and 65 years of age and no current pregnancy or immunodeficiency, Absence of focal, complicated or chronic forms of brucellosis and the absence of concomitant diseases

Intervention groups

In this trial, patients in the intervention group received one probiotic capsule daily from the day of treatment for 60 days, and patients in the control group received one placebo capsule daily during this period. Both groups are under antibiotic treatment of the disease, which is used similarly for both groups.

Main outcome variables

The duration of fever, chills, musculoskeletal pain, anorexia, nausea, esophagitis, diarrhea and weakness of the patient, which is asked by phone call to the patient every day from the first day of treatment until the symptoms are resolved, and recorded in the patient's checklist. Wright and Coombs-Wright, 2ME, ESR and CRP titer, which are measured at the beginning and 60 days after the start of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240130060856N1**
Registration date: **2024-02-13, 1402/11/24**
Registration timing: **prospective**

Last update: **2024-02-13, 1402/11/24**
Update count: **0**

Registration date

2024-02-13, 1402/11/24

Registrant information

Name

Seyyed Amirhossein Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

mosavia7777@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of probiotic supplementation on clinical manifestations and laboratory findings and the treatment process of patients with Brucellosis: A triple-blind randomized controlled trial

Public title

Investigating the effect of probiotic supplementation on Brucellosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with new onset Brucellosis

Exclusion criteria:

Presence of immunodeficiency in the patient Taking immunosuppressive drugs Presence of concomitant diseases such as tuberculosis, malignancy, liver cirrhosis and ESRD Current pregnancy Presence of focal, complicated or chronic forms of Brucellosis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, for the random distribution of the samples between the intervention and control groups, the web-based randomization method is used, and based on the size of the study sample, two groups with equal numbers of numbers are generated, after sorting the numbers of each group from small to Large, the groups are called group A and group B, and one group is randomly assigned to the intervention group and the other one to the control group. During the sampling, new patients with Brucellosis who meet the inclusion criteria are numbered in the order of entry and based on the mentioned grouping, each patient is randomly placed in group A or B.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the researchers, the study participants and the analyst are not aware of the random allocation method until the completion of the statistical analysis. Before the start of sampling, the process of randomization is carried out by the secretary of the infectious disease clinic using the aforementioned method to randomly assign the samples in two groups A and B, as well as packaging the drugs in similar cans and numbering them. Due to the placement of drugs in similar cans and only put the patient's number on the cans, the patients in both intervention and control groups as well as the researchers are unaware of the contents of the cans, which contain probiotic capsules or placebo. Also, the data is delivered to the analyzer in the form of two groups A and B, and the analyzer is not aware of the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Siences, Basij Sq., Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2024-01-07, 1402/10/17

Ethics committee reference number

IR.ARAKMU.REC.1402.205

Health conditions studied

1

Description of health condition studied

Brucellosis

ICD-10 code

A23

ICD-10 code description

Brucellosis

Primary outcomes

1

Description
Duration of fever
Timepoint
Daily from the beginning of the intervention until the symptom disappears
Method of measurement
Patient checklist

2

Description
Duration of chills
Timepoint
Daily from the beginning of the intervention until the symptom disappears
Method of measurement
Patient checklist

3

Description
Duration of musculoskeletal pain
Timepoint
Daily from the beginning of the intervention until the symptom disappears
Method of measurement
Patient checklist

4

Description
Duration of anorexia
Timepoint
Daily from the beginning of the intervention until the symptom disappears
Method of measurement
Patient checklist

5

Description
Duration of weakness
Timepoint
Daily from the beginning of the intervention until the symptom disappears
Method of measurement
Patient checklist

6

Description
Duration of diarrhea
Timepoint
Daily from the beginning of the intervention until the symptom disappears
Method of measurement
Patient checklist

7

Description
Duration of nausea
Timepoint
Daily from the beginning of the intervention until the symptom disappears
Method of measurement
Patient checklist

8

Description
Duration of esophagitis
Timepoint
Daily from the beginning of the intervention until the symptom disappears
Method of measurement
Patient checklist

9

Description
Wright
Timepoint
At baseline and 60 days after the initiation of trial
Method of measurement
Laboratory kit

10

Description
Coombs Wright
Timepoint
At baseline and 60 days after the initiation of trial
Method of measurement
Laboratory kit

11

Description
ESR
Timepoint
At baseline and 60 days after the initiation of trial
Method of measurement
Laboratory kit

12

Description
CRP
Timepoint
At baseline and 60 days after the initiation of trial
Method of measurement
Laboratory kit

13

Description
2ME
Timepoint
At baseline and 60 days after the initiation of trial
Method of measurement
Laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily taking of one Lactocare probiotic capsule containing 10^9 CFU of bacteria for 60 days
Category
Treatment - Drugs

2

Description
Control group: Daily taking of one placebo capsule containing wheat starch for 60 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational-therapeutic centers of Arak city
Full name of responsible person
Seyyed Amirhossein Mousavi
Street address
Arak University of Medical Siences, Basij Sq., Arak, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Davoud Hekmat Pou
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Seyyed Amirhossein Mousavi
Position
Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Position

Assistant Professor

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Infectious diseases

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Person responsible for updating data

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Seyyed Amirhossein Mousavi

Position
Intern

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available